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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,063	12/26/2001	Audrey Goddard	P3030R1C6	4326
30313 7590 09/14/2007 KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET IRVINE, CA 92614			EXAMINER KOLKER, DANIEL E	
			ART UNIT 1649	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/036,063

Applicant(s)

GODDARD ET AL.

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All \* b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. The remarks and declaration filed 10 July 2007 have been entered. No claims have been amended. Claims 22 – 26 and 28 – 30 are pending and under examination.

### ***Priority***

2. Applicant is reminded that the effective filing date of all pending claims is 1 March 2000, the date that PCT/US00/05601 was filed. While the protein of SEQ ID NO:57 was disclosed previously, and antibodies to such protein were disclosed previously as well, 1 March 2000 is the date of the first filing of an application that showed how to use this protein. Prior to such dates, the filings reported the sequence only but not how to use either the protein or the antibodies that bind thereto.

Applicant did not traverse the examiner's determination that this is the first date that a patent application was filed which discloses how to use the protein of SEQ ID NO:57.

### ***Maintained Rejections***

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22 – 25 and 28 – 29 stand rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (WO 99/58660, of record, "Ruben I").

This rejection stands for the reasons of record. Ruben teaches a protein over 99% identical to applicant's SEQ ID NO:57 and teaches antibodies to same. The reasons why the antibodies from Ruben I meet the limitation of each of claims 22 – 25 and 28 – 29 have been set forth previously and for the sake of brevity will not be reiterated. Applicant has not traversed the

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examiner's determination that the reference teaches every element of claims 22 – 25 and 28 – 29, but rather has presented arguments as to why the declarations, including that newly-filed on 10 July 2007 and those previously made of record, together with the provisional application, should be sufficient to antedate the reference.

Applicant argues, in the remarks filed 10 July 2007, that the newly filed declaration and the provisional application together provide evidence that applicant was in possession of the antibodies now claimed prior to April 21 1999 (remarks, p. 4, first complete paragraph; declaration filed 10 July 2007, paragraph 5).

The declaration filed on 10 July 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Ruben I reference. Contrary to applicant's statements above, the declaration fails to show possession of the antibodies. The evidence supplied with the declaration clearly show possession of the nucleic acid of SEQ ID NO:56 (Exhibit A). Nucleic acids are not what is claimed herein; antibodies are. Thus Exhibit A is insufficient to provide evidence of possession. Exhibit B provides evidence of possession of the protein of SEQ ID NO:57. As set forth previously, it is uncontested that the evidence of record indicates applicant was in possession of the protein of SEQ ID NO:57 prior to 10 November 1999. However, neither of the exhibits provides evidence of possession of the antibody.

Applicant states, at p. 5 first paragraph of the remarks filed 10 July 2007, that Ruben contemplates but does not make antibodies to the relevant sequence. The examiner respectfully disagrees with applicant's characterization of the Ruben reference. At p. 49 lines 8 – 10 Ruben teaches antibodies to the relevant sequence. At p. 49 lines 17 – 20, Ruben teaches specific epitopes within the protein to which antibodies should be raised. At pp. 195 – 197, Ruben teaches how to make antibodies. While applicant is convinced that this is prophetic and does not provide evidence of possession of the antibody, the examiner can find no reason to believe that the disclosure is prophetic rather than a description of reduction to practice. Ruben was published before the effective filing date of the instant claims, and teaches what is now claimed. The declaration fails to provide evidence of possession of antibodies. Therefore the declaration is not sufficient to antedate the reference and overcome the rejection. While applicant had contemplated antibodies in the provisional application, which does in fact antedate the Ruben I reference, priority is not granted to the provisional application as it does not comply with 35 USC 112, first paragraph because it does not disclose how to use the invention now claimed.

Applicant also refers to the Written Description Guidelines, particularly Example 16, which is on the topic of antibodies. Applicant argues that this example provides support for the argument that disclosure of the protein sequence is sufficient to provide evidence of possession of the antibody that binds to that protein. The examiner respectfully disagrees. The subject of the document from which the example is drawn is the written description requirement of 35 USC 112, first paragraph. The document does not address whether non-enabling disclosures of antibodies, such as in the provisional application, are sufficient to overcome rejections under 35 USC 102(a). The discussion of "implicitly disclosed" antibodies in Example 16 of the written description guidelines is not the same as whether or not one was in possession of the invention.

4. Claims 22 – 25 and 28 – 29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ruben (US Patent Application Publication 2003/0100051, of record, effective filing date 10 November 1999; "Ruben II").

This rejection stands for the reasons of record and explained in further detail herein. The disclosure of Ruben II is substantially the same as that of Ruben I. To the extent that the examiner has determined that the declarations and arguments are insufficient to overcome the rejection of Ruben I under 35 USC 102(a), they also apply to the rejection over Ruben II under 35 USC 102(e).

In addition, should the declarations later be found sufficient to antedate the Ruben I reference, the rejection over Ruben II would still stand for the following reasons. The declaration filed on 10 July 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Ruben II reference. The Ruben II reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP Chapter 2300. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

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***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22 – 26 and 28 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben (WO 99/58660) in view of Holmes (Current Protocols in Immunology, of record).

This rejection stands for the reasons previously made of record. In the remarks filed 10 July 2007, applicant did not traverse the examiner's determination that the claims are obvious over the teachings of the two references, but rather argued that Ruben I does not qualify as prior art under 35 USC § 102. Applicant did not explicitly address the rejection over Ruben I in view of Holmes. As explained in paragraph number 3 above, Ruben I anticipates claims 22 – 25 and 28 – 29; therefore the reference qualifies as prior art under §§ 102 and 103 and the rejection stands.

6. Claims 22 – 26 and 28 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben (US Patent Application Publication 2003/0100051) in view of Holmes (Current Protocols in Immunology, of record).

This rejection stands for the reasons previously made of record. In the remarks filed 10 July 2007, applicant did not traverse the examiner's determination that the claims are obvious over the teachings of the two references, but rather argued that Ruben II does not qualify as prior art under 35 USC § 102 and thus is not available as prior art under § 103. As explained in paragraph number 4 above, Ruben II anticipates claims 22 – 25 and 28 – 29; therefore the reference qualifies as prior art under §§ 102 and 103 and the rejection stands.

***Conclusion***

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

September 11, 2007



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER